

EXHIBIT B

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WISCONSIN

This Document Relates to:

Boyer v. Weyerhaeuser Company, et al.
Masephol v. Weyerhaeuser Company, et al.
Pecher v. Weyerhaeuser Company, et al.
Sydow v. Weyerhaeuser Company, et al.

CASE NO. 14-cv-286
CASE NO. 14-cv-186
CASE NO. 14-cv-147
CASE NO. 14-cv-219

DECLARATION OF JAMES S. JOHNSON PhD, CIH, QEP
IN REBUTTAL TO THE SECOND AFFIDAVIT OF PHILLIP EIZTMAN

I, JAMES S. JOHNSON PhD, CIH, QEP, declare as follows:

1. My background, education, work history and qualification have been set forth in an early declaration in this case.

2. I have been asked comment on the Second Affidavit of Philip Eitzman dated September 17, 2015. All references to paragraphs below refer to Eitzman's Second Affidavit.

3. Paragraph 4 thereof asserts that the 3M 8710 respirator maintained uninterrupted NIOSH certification based on its established compliance with the law. I disagree. In my previous Expert Reports, Declaration and items addressed in this Rebuttal, I present reasons why 3M was not in compliance with the law (NIOSH certification/approval regulations) for the 3M 8710 respirator and if this information had been provided to NIOSH the 8710 respirator approval would have been withdrawn until compliance was properly demonstrated.

4. Paragraph 5 thereof asserts that pressure drop does not lead to face seal leakage. I disagree based on my comments made in my Declaration in Rebuttal to the Second Weber Affidavit.

5. I disagree with the conclusion drawn by Eitzman in his paragraph 6 regarding the Nancy Bollinger Memo re “Audit of the 3M 8710 respirator”, dated November 12, 1980 (Exhibit B to 2nd Eitzman affidavit).

(a) What is clearly lacking from 3M in response to this audit finding is the reporting of 3M’s ongoing inhalation and exhalation manufacturing problems with the 3M 8710 respirator. The communication by 3M of these types of problems to NIOSH is clearly required by 30 CFR Part 11. (Ex. 27, 30, 39)

(b) Bollinger notes in Exhibit B that additional respirators should be purchased and evaluated to see how prevalent the problem is. The fact that 3M didn’t communicate their manufacturing problems with inhalation and exhalation pressure drop at this time to NIOSH or call to Miss Bollinger’s attention the undated memo to file of Mr. Robert Schutz (Exhibit C to Eitzman 2nd Affidavit) clearly illustrates the violation of the approval process.

6. The information noted in paragraph 7 by Eitzman is incomplete and draws the wrong conclusions from Exhibit C (Eitzman 2nd affidavit).

(a) The 3M internal field letter by E. D. Horne to D. J. MacDonald (Ex. 26) provides the correct background and context on how the Schutz memo (Exhibit C to Eitzman 2nd affidavit) should be interpreted. The first paragraph of Exhibit 26 concludes that as a result of a NIOSH audit in April 1975, the current 3M 8710 could not meet the certification requirements for the final inhalation and exhalation pressure drop requirements. Knowing this and evidently not providing this information to NIOSH, 3M started negotiations. On a visit to 3M, Pat Gussey, Head of the Respirator Testing at

Morgantown agreed to test “1972 product history samples” on the Morgantown silica dust test apparatus. Exhibit 26, second paragraph.

(b) Exhibit C (Eitzman 2nd Affidavit) Mr. Schutz noted “as a result of silica dust tests on the 3M 8710 respirator conducted in the spring of 1975, 3M was advised that their 8710 respirator failed to meet applicable silica dust requirements. This was confirmed through further testing.” This is a clear reference to the April 1975 audit mentioned in Exhibit 26 and the need for further testing. It is clear that the testing of the “1972 product history samples” produced the results he refers to as “confirmed through further testing” in his second sentence. Schutz then noted there were humidity concerns with the move of the silica dust chamber to Morgantown and a new humidity operating range was recommended of 40 to 60% relativity which is still in the regulatory range of 20 to 80 percent, Exhibit 26 item (1 & 4). Mr. Schutz also noted in the undated Exhibit C that 3M indicated they were redesigning the 3M 8710 respirator (8710H) to meet the new criteria. Schutz also noted that the 3M 8710 respirator meets the criteria under which it was approved and no further action will be taken at this time. Eitzman extracts from this letter that NIOSH was aware of the pressure drop issues. This is not the rest of the story. The only thing NIOSH knew was due to a change in location of the silica dust chamber there were pressure drop issues with the 3M 8710 respirators. As noted in Exhibit 26, item (2), 3M assured NIOSH they were making the same respirator as was originally being tested which was not true.

(c) 3M also requested that NIOSH have their QC people keep this pressure drop information from 3M’s competitors who would understand the problems and especially from their trade organization ISEA. It is my opinion that this meeting where

3M was not forthright with NIOSH permitted 3M to continue to cover up their 3M 8710 respirator approval problems.

(d) Exhibit 26 item (7) states “we hope to submit the 8710H product in late July for certification”. Exhibit 26 item (8) revealed (1) 3M’s clear understanding that the 3M 8710 and 8710H had problems with the final pressure requirements and (2) Mr. Schutz of NIOSH expected the silica dust test values to be met.

7. In paragraph 8 Eitzman discusses quality control plan classifications of respirator defects. He contends breathing resistance (which causes facial leakage) is Major B, rather than Major A. *These specific categories are in 30 CFR Part 11 and were included in the quality control program that 3M submitted to NIOSH and was approved then becoming part of the approval requirements.* (Exs. 1, 39, 49). Eitzman contends that pressure or breathing resistance of a respirator such as the 3M 8710 respirator was detectable by the user, thus he contends breathing resistance and pressure drop is a major B characteristic. Eitzman presents no evidence or references to support his claim that the pressure drop or breathing resistance of the 3M 8710 respirator is detectable by the user. I am aware of no published studies that address this subject for the 3M 8710 respirator. The exhibits referenced above conflict with Dr. Eitzman’s contention and clearly shows 3M recognized pressure drop as a Major A defect and 3M was selling 3M 8710 respirators that didn’t comply with NIOSH quality control approval requirements. (Exs. 15, 39).

8. In paragraph 9, Eitzman makes the general statements that “3M engaged in an ongoing process to calibrate its own test machines to NIOSH machines to achieve consistent, reliable results. 3M’s purpose in this process was to conform to NIOSH requirements not evade them.” Internal 3M correspondences do not support these statements and in fact the

available information reflects just the opposite. There is no correspondence I am aware of that indicates any development information or 3M changes to their silica dust apparatus or the DOP test apparatus *were shared with NIOSH*. And none is presented by 3M.

9. The statement made by Eitzman in paragraph 10 is not backed up with any reference material. He claims “in the early 1970s manufacturers of NIOSH approved respirators began to use dioctyl phthalate (DOP) aerosol in testing respirators as a substitute for the silica dust test in their quality control plans.” I am aware of only one manufacturer, 3M who received approval to use it as a surrogate for the silica dust test.

10. In paragraph 11, Eitzman states that NIOSH directly or through its consultants suggested that 3M should correlate a DOP-based test to the silica dust test and use the DOP in lieu of (or as a surrogate for) the silica dust test. I have seen no correspondence that indicates NIOSH was involved in the initial decision process rather it was 3M that initiated this approach.

11. In paragraph 12 and 13, Eitzman again notes that “3M was not required to conduct silica dust testing of the 3M 8710 respirator except as required for extensions of NIOSH approval deemed to require filter performance data.” He also notes that there was no requirement for 3M to follow 30 CFR Part 11 after 1972, but he provides no supporting back up reference material. Eitzman’s contention that there was no requirement to follow NIOSH silica dust regulations is incorrect because 3M was responsible to demonstrate their DOP /silica dust correlation was still valid. 30 C.F.R. § 11.34 (Ex. 1); Ex. 20.

12. In paragraph 14 Dr. Eitzman attempts to dismiss all of the internal correspondence and meetings that pointed out problems with the 3M 8710 respirator manufacturing processes, meeting NIOSH certification requirements, criticizing the DOP test

and changing pass/fail correlations, issues with the silica dust test, correlations of multiple silica dust chambers, etc. He notes, “These discussions did not address the correlation between the DOP test and the silica dust test conducted for the original product approval.” What Eitzman fails to recognize is the responsibility of 3M to meet the requirements and conditions under which the 3M 8710 respirator was approved and if not inform NIOSH of the issue/problem.

13. In paragraph 15, Eitzman takes exception with the interpretation of Exhibit 14 that clearly points out in 1973 a major manufacturing problem and states: “Production is currently gambling by using this web in full production.” This unidentified problem is clearly impacting the production of an acceptable slit web that can meet the required pressure drop specification for the manufacture of the 3M 8710 respirator.

14. I have reviewed Eitzman’s paragraph 16 wherein he discusses paragraphs 51-61 in Ms. Segawa’s Proposed Findings of Fact as well as Plaintiff Exhibits 15-19 and I find the issues identified in these exhibits as major.

(a) Eitzman notes these as temporary production issues that were resolved. To the contrary, 3M by excluding NIOSH in all of these issues violated their quality assurance plan for the 3M 8710 respirator approval and there is no documentation of how each process problem identified was resolved or if it was resolved.

(b) Exhibit 15’s statement that the DOP “correlation is no longer valid” is clearly a significant event that would indicate the product wasn’t meeting NIOSH approval parameters and the process should have been shut down until corrected and the problem(s) brought to NIOSH’s attention.

15. In paragraph 17, Eitzman comments on exhibits 21 and 22 of Ms. Segawa's Proposed Findings of Fact. Clearly 3M had major manufacturing problems with making the 3M 8710 respirators comply with the NIOSH quality assurance requirements.

(a) On January 16, 1975 Don Wilmes (Ex. 21) changed the acceptable limits for the three web laminates and the finished mask (3M 8710 respirator). With the instructions that the limits are in effect beginning 1-20-75 and will be reviewed after 30 days based on the results of his audits and waste levels.

(b) There is no evidence that NIOSH was informed on these major production issues and changes, a clear violation of the quality control plan and 3M was content with selling respirators that met the modified DOP test but failed the silica dust test.

16. In paragraph 18, Eitzman identified the results reported in the various letters (Ex. 28-31, 33-37) ranging from June of 1975 to through December of 1977 as the result of NIOSH changes to the silica dust testing chamber and not major design flaws and other process changes with the 3M 8710 respirator. This excuse is a totally bogus reason that 3M has used during this time period and clearly Mr Schutz didn't identify any significant changes and expected 3M to meet the silica dust test requirements as I noted in paragraph 6(d)(2). In the five letters, exhibits 15-19 I identified in paragraph 14, 3M was clearly having manufacturing problems that should have been reported to NIOSH.

17. In paragraph 19, Eitzman states plaintiffs misunderstand Exhibit 39. He notes that NIOSH approved 3M's use of the DOP test as a substitute for the silica dust test. This approval was based on a specific data set that provided a correlation of the silica dust and DOP test results for 3M 8710 respirators manufactured at that time. As with any other part of the approval process for the 3M 8710 respirator any changes to the NIOSH approved correlation

values would require review and approval by NIOSH. 3M made a number of changes over the years to both the 3M 8710 respirator manufacturing process and these correlations without submitting them to NIOSH for review and approval. Exhibit 39 is an example of one those changes that was not submitted to or approved by NIOSH.

18. In paragraph 20, Eitzman notes that 3M had multiple silica dust chambers and the changes described were being made were to obtain closer agreement in test results and test protocols. He notes that there is no guidance provided in 30 CFR Part 11 on compressed air provided to the chamber so it was not regulated. This is in direct contrast to the 3M complaint to NIOSH about a humidity change in moving the chamber from Pittsburgh to Morgantown. As a result of this move NIOSH recommended the humidity be controlled to 40 to 60% rather than the regulatory requirement of 20 to 80% relative humidity. Clearly the internal 3M correspondence shows that their silica dust chambers were modified by reducing the humidity of the compressed air supplied to the chamber, controlling the humidity of all incoming air, and adding instruments to permit the monitoring of charge on the silica dust particles as well as adjustments to the silica dust generator. There is no indication that any of these modifications were discussed with NIOSH or communicated to them in writing.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is correct.

DATED: 10/12/15.

Respectfully submitted,


JAMES S. JOHNSON PhD, CIH, QEP